REMARKS

In the specification, the paragraphs [0042], [0069], [0075], and [0076] have been amended to properly identify trademarks. MPEP 608.01(v) requires trademarks to either be capitalized or followed by the registered trademark symbol. The Applicants have inserted a registered trademark symbol after trademark terms.

In addition, paragraph [0033] has been amended to correct the chemical name of Polyquaternium 1® to poly[(dimethyliminio)-2-butene-1,4-diyl chloride], α-[4-[tris(2-hydroxyethyl) ammonio]-2-butenyl]-ω-[tris(2-hydroxyethyl)ammonio]-dichloride. Support for this amendment may be found, *inter alia*, in the same paragraph, wherein it provides the Chemical Registry Number 75345-27-6 and the trademark name, Polyquaternium 1®. The accompanying CAS registry lists the chemical name as presently amended as well as the CAS registry number and the trademark name as disclosed in the originally–filed specification.

The Applicants hereby affirm the telephonic election of Group I, claims 1-13, 21-46, and 55-57, without traverse. Claims 1-13, 21-46, and 55-57 are pending in this application. Claims 14-20 and 47-54 have been withdrawn for being drawn to a non-elected invention. Claims 3 and 26 have been cancelled. The Applicants retain the right to present claims 14-20 and 47-54 in a divisional application.

35 U.S.C. §112 Rejections

Claims 3, 26 and 38 stand rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office objected to the use of trademarks in claims 3 and 26. The Applicants have canceled claims 3 and 26.

In addition, the Office rejected claim 38 since it depended from superseding claim 44. The Applicants have amended claim 38 to depend from claim 34, a preceding claim.

Withdrawal of these rejections is respectfully requested.

35 U.S.C. §103 Rejections

Claims 1-13, 21-46, and 55-57 are rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,482,799 ("Tuse") in view of U.S. Patent Publication No. 2003/0228393 ("Zhao"), U.S. Patent Publication No. 2003/0105167 et al ("Dykens"), and U.S. Patent Publication No. 2004/0120916 ("Huth"). The Applicants respectfully traverse.

The Applicants surprisingly have discovered that the antimicrobial activity of CPC is reduced by certain non-ionic surfactants (e.g., Tween 80) that are commonly used in ophthalmic solutions. [See, e.g., Specification, p. 26, Table 2 and lines 1-3]. Meanwhile, the Applicants also surprisingly discovered that a synergy exists between CPC and other non-ionic surfactants (i.e., poly(oxypropylene)-poly(oxyethylene) block copolymers). [See, e.g., Specification, pp. 26-27, compare results in Tables 2 & 3]. In order to arrive at the present claims, a skilled artisan would have to select about 0.1 to about 10 ppm CPC to combine with poly(oxypropylene)-poly(oxyethylene) block copolymers. The Applicants respectfully submit that a skilled artisan would not have been led to the present claims based on the singular or combined disclosures of Tuse, Zhao, Dykens, and Huth. The Office has failed to make a *prima facie* case of obviousness.

Every limitation of the present claims must be found in the prior art. None of the cited references disclose about 0.1 to about 10 ppm CPC in accordance with independent claims 1, 8, 21, 22, and 34 or about 0.1 to about 2 ppm CPC in accordance with independent claim 55. Although pages 11-12 of the Office Action state that "the amounts of cetylpyridinium chloride, . . . are all known in the art and it is simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed amounts," the present claims are directed to subject matter that cannot be devised using "routine optimization," particularly based on the cited references. The Office has not given adequate consideration to the process a skilled artisan must go through to

arrive at the present claims from the cited references. In other words, the Office has used hindsight reconstruction.

First, the skilled artisan must choose poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants from a myriad of available ophthalmic surfactants. Next, the skilled artisan must select CPC from another myriad of available preservatives. Tuse is directed primarily to "an antimicrobial peptide that is an indolicidin . . . ." [Tuse, Abstract]. If a skilled artisan were to experiment with anything related to antimicrobials based on Tuse, it would be with the various indolicidins and/or their concentrations. Further, Tuse alone discloses CPC in a list of about forty (40) other preservatives, with no emphasis on CPC. [Tuse, column 17, lines 35-51]. Beyond providing no motivation for a skilled artisan to select CPC, Tuse actually teaches away from using CPC (or any other preservative) in a composition that will come in direct contact with the eye.

Specifically, Tuse states that a "preservative may be added for the purpose of reducing the necessary concentration of indolicidins, particularly where the solution is not expected to come into direct contact with the eye. It is noted however, that many such preservatives are eye irritants and/or toxic. If preservatives are employed, the contact lens is preferably rinsed prior to insertion into the eye." [Tuse, column 17, lines 23-29]. The present claims are directed to multi-purpose solutions, which are capable of, *inter alia*, disinfecting, storing and rinsing contact lenses without resort to additional solutions. A skilled artisan would not prepare a multi-purpose solution with a component that the art teaches may be toxic and should "not come into contact with the mouth and/or skin and/or eye." [Tuse, column 17, lines 30-35]. Contrary to Tuse' teaching, commercial embodiments of the present claims will be capable of contacting the mouth and skin and eye.

After the skilled artisan selects poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants and acts contrary to Tuse' teaching and selects CPC, the skilled artisan must then determine the amount of CPC to use. None of the cited references provides even an inkling of how much CPC to use in the solutions. The present claims, however, are directed to a specified amount of CPC in combination with

poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants. Determining the amount of CPC to be in the range of about 0.1 to about 10 ppm is not routine. Indeed, without any guidance or a starting point, determining the amount of any component down to a parts per million level cannot be said to be routine.

Zhao, Dykens, and Huth also do not disclose 0.1 to about 10 ppm CPC in combination with poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants. Since the Office has failed to show why a skilled artisan individually would select CPC and poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants from the myriad of available ophthalmic components and since none of the cited references provide any suggestion for a skilled artisan to use about 0.1 to about 10 ppm (or any amount for that matter) of CPC in combination with poly(oxypropylene)-poly(oxyethylene) block copolymer surfactants, the Office has failed to establish a prima facie case of obviousness. Accordingly, the Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment, or credit any overpayment, to Deposit Account No. 502317.

Respectfully submitted,

Dated: November 21, 2007

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Onamer M

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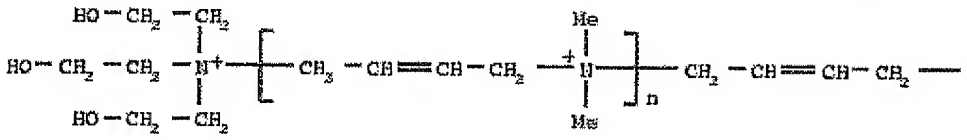
ANSWER 1 © 2003 ACS

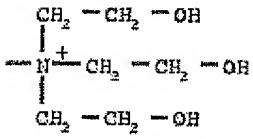
Structure Diagram

PAGE 1-A



• 3 Cl⁻

PAGE 1-B



CAS Registry Number

75345-27-6 REGISTRY

Deleted Registry Number

68518-54-7, 77539-07-2, 79078-20-9, 83635-69-2

Chemical Name

Poly[(dimethyliminio)-2-butene-1,4-diyl chloride], .alpha.-[4-[tris(2-hydroxyethyl)ammonio]-2-butenyl]-.omega.-[tris(2-hydroxyethyl)ammonio]-, dichloride (9CI) (CA INDEX NAME)

Onamer M

Onyxsperse 12S

Polidronium chloride

Polyquad

Polyquaternium 1

Molecular Formula

(C6 H12 N)n C16 H36 N2 O6 . 3 Cl

CAS REGISTRY

Search for information related to CAS RN **75345-27-6** in these categories:

- Agriculture [$2.00]
- Biotechnology [$2.00]
- Business [$2.00]
- Chemical Substances [$2.00]
- Chemistry References [$2.00]

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